



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,275	09/24/2003	Vaclav Dusek	14358-00176	9374
33357	7590	06/07/2006	EXAMINER	
ADVANCED MEDICAL OPTICS, INC. 1700 E. ST. ANDREW PLACE SANTA ANA, CA 92705				ANDERSEN, MICHAEL T
		ART UNIT		PAPER NUMBER
		3734		

DATE MAILED: 06/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/672,275	DUSEK ET AL.	
	Examiner	Art Unit	
	M. Thomas Andersen	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 03 March 2006.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-23 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-23 is/are rejected.
 7) Claim(s) 1 and 13 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Acknowledgement is made of the remarks filed 03/03/2006. The arguments have been taken into consideration. The examiner is persuaded by applicant's arguments that Chambers does not anticipate applicant's invention under 35 U.S.C. 102(b) because the "lower groove for receiving an inwardly extending protrusion of a cylindrical barrel 12" cannot reasonably be considered a latch finger and latch pin. See Chambers, column 6, lines 10-16.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 19, and 22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9, 2, 13, and 24, respectively, of copending Application No. 10/412,431 in view of **Figueroa et al. (5,873,879)**. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following:

Claim 1: It would be obvious to use some sort of latch device, e.g. a latch and latch finger, as a positioning device that prevents movement because Figueroa uses such a device to prevent proximal longitudinal movement.

Claim 2: Claim 9 of 10/412,431 claims a spring plunger, and it would be obvious to use a helical compression spring as a type of spring plunger because a helical compression spring appropriately fits around the plunger and within the outer housing.

Claim 19: As mentioned above, it would be obvious to use a latch and pin mechanism in view of Figueroa as a locking mechanism as claimed in claim 2 of 10/412,431.

Claim 22: A "latch finger and a latch pin" is one example of "a latching means and a locking means" (claim 13 of 10/412,431). In view of Figueroa, it would be obvious to use a latch finger and pin as a latching means and locking means.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

Claims 1, and 13 are objected to because of the following informalities: "lateral" should likely read "longitudinal". Appropriate correction is required.

Specification

The disclosure is objected to because of the following informalities: page 7, last line, "treaded" should read "threaded".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by **Weber et al.**, U.S. Patent No. 6,899,717 (hereinafter “**Weber**”). Weber discloses methods and apparatus for delivery of ocular implants.

Claims 1 and 22: Figures 11A-11B show a plunger rod 148 in communication with an inserter housing (near 101), a first drive mechanism 172 for providing contact between and causing longitudinal movement of said plunger rod assembly and said intra-ocular lens, a latch pin 175 and a latch finger (161 in combination with 176) configured for engagement with said latch pin for preventing proximal longitudinal movement of said plunger rod assembly so that said intraocular lens may be accurately positioned within said eye.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Chambers**, U.S. Patent No. 6,059,791, in view of **Figueroa**, U.S. Patent No. 5,873,879.

Regarding claim 1, Chambers discloses a plunger rod assembly in communication with an inserter housing, said inserter housing adapted to house an intraocular lens (Chambers, col. 3, lines 37 -40); a first drive mechanism for providing

contact between and causing longitudinal movement of said plunger rod assembly and said intraocular lens within said inserter housing (Id. at col. 3, lines 48 - 50). Chambers does not expressly disclose a latch pin and latch finger system for preventing proximal longitudinal movement of said plunger rod assembly. However, Figueroa discloses, “[t]o avoid inadvertent release of the haptic lens during shipping and storage, the plunger could be secured in a fixed position through the use of a latch.” Figueroa, column 6, lines 20-23. It is clear that the purpose of the latch in Figueroa is to prevent proximal longitudinal movement of the plunger assembly, and thus prevent inadvertent movement of the haptic. It is obvious that such a latch disclosed by Figueroa would comprise something that can be considered a “pin” and “finger” because another latch system that Figueroa uses in figure 13 can be said to comprise a “pin” and “finger” which connects the proximal end 93 of the cannula to the base member 20. Figueroa discloses, “A hole 104 defined at the proximal end 93 of cannula 22 cooperates with a biased lock 106 on base member 20 to secure the cannula in place.” Figueroa, column 5, lines 3-5. The proximal end 93 of the cannula with the hole 104 can be considered a latch finger and the biased lock 106 (properly labeled in figure 14) can be considered a latch pin. It is interpreted that a similar configuration would be used to prevent “inadvertent release of the haptic lens.” Figueroa, column 6, lines 20-21. It would be obvious to combine Chambers with Figueroa because they are both directed to delivering intra-ocular lenses, and Figueroa overcomes the weakness in Chambers, the weakness being not having anything to prevent inadvertent movement of the haptic lens.

Regarding claim 2, Chambers discloses that the plunger rod assembly further comprises a push rod (16) and a helical compression spring (24) in biasing relation to said push rod (col. 3, lines 58 - 61).

Regarding claim 3, Chambers discloses that the plunger rod assembly further comprises a barrel (12) within which said push rod (16) is slideable, wherein said barrel (12) has a proximal pad and said push rod (16) has a proximal part having a slide disc disposed thereon and said helical compression spring (24) is slideable along said rod (16) proximal pad between said barrel (12) proximal part and said slide disc.

Regarding claim 4, Chambers further discloses a transversely projecting finger support (20) secured to said barrel (12).

Regarding claim 5, the plunger rod assembly in Chambers further comprises a knob (22) having external threads rotatably secured to said push rod (16) (col. 5, lines 61 - 63), wherein said barrel (12) comprises inwardly projecting pins and wherein said external threads cooperate with said inwardly projecting pins (col. 6, lines 10 - 12).

Regarding claim 6, the plunger rod assembly in Chambers further comprises a barrel (12) within which said push rod (16) is slideable, said barrel (12) further comprising a slot (14). Figueroa discloses that the latch finger can be carried on the barrel (similar to securing the proximal end 93 of the cannula to the base member 20 or barrel), and the latch finger can be carried by the push rod (See Figueroa, column 6, lines 20-23).

Regarding claim 7, Chambers further discloses that the plunger rod assembly further comprises a knob (22) having external threads rotatably secured to said push

rod (16) (col. 5, lines 61 - 63), wherein said barrel comprises inwardly projecting pins (col. 6, lines 11 - 12), and wherein said external threads cooperate with said inwardly projecting pins (col. 6, lines 10 - 11).

Regarding claim 8, the axial extent of said external threads along said knob is limited and said external threads thereby cooperate with said inwardly projecting pins over a limited distance (col. 6, lines 25 - 30).

Regarding claims 9 and 18, as mentioned in regard to claim 1, Chambers does not disclose a latch pin and latch finger. However, it would be obvious to use a latch pin and latch finger system as disclosed in Figueroa. The latch finger and latch pin configuration in Figueroa used to secure the proximal end of the cannula 93 to the base member or barrel 20 can obviously be used on the plunger itself to secure or prevent its movement relative to the barrel 20, and thus prevent inadvertent movement of the haptic lens. It would be obvious to use this configuration on the plunger because Figueroa discloses “[t]o avoid inadvertent release of the haptic lens during shipping and storage, the plunger could be secured in a fixed position through the use of a latch.” Figueroa, column 6, lines 20-23. Such a configuration comprises a ramp (shown as 106 in Figueroa's figure 14) and a notched segment (104 in figure 13, or 102 in figure 14).

Regarding claim 10, Chambers discloses a cartridge housed within said inserter housing, said cartridge having a folded intraocular lens positioned therein (col. 3, lines 42 - 45).

Regarding claim 11, in Chambers, the plunger rod assembly further comprises a barrel (12) within which said push rod (16) is slideable, wherein said barrel (12) has a

distal portion, and wherein the device further comprises a cartridge having folded intraocular lens positioned therein (col. 3, lines 36 - 37), wherein said cartridge is fitted into said distal portion of said barrel (12) (col. 5, lines 39 - 40).

Regarding claim 12, the barrel (12) has an interior bore and an exterior, and said distal portion of said barrel (12) has an axial slot (14) communicating between said interior bore and said exterior, and said bore allows said cartridge to be inserted downward into said bore of said barrel (12) (col. 5, lines 39 - 40).

Regarding claim 13, Chambers discloses a barrel (12) having a proximal portion, a distal portion having an axial slot (14), and an interior bore; a push rod (16) having a proximal part and a slide disc disposed thereon, said push rod (16) slideable within said bore of said barrel (12); a helical compression spring (24) slideable along said proximal part of said rod (16) between said proximal pad of said barrel (12) and said slide disc; a cartridge having a folded intraocular lens positioned therein (col. 3, lines 42 - 45), wherein said cartridge is fitted into said axial slot (14) on said distal portion of said barrel (12) (col. 5, lines 39 - 40); a first drive mechanism for providing contact between and causing longitudinal movement of said push rod (16) and said intraocular lens within said lens cartridge (col. 5, lines 39 - 41; col. 3, lines 37 – 40; lines 47 - 50). Regarding the latch pin and a latch finger configured for engagement with said latch pin for preventing proximal longitudinal movement of said push rod so that said intraocular lens may be accurately positioned within said eye, see the rejection to claim 1.

Regarding claim 14, Chambers further discloses a transversely projecting finger support secured to said barrel (12) (col. 6, lines 11 - 12).

Regarding claim 15, the push rod (16) in Chambers further comprises a knob (22) having external threads rotatably secured to said proximal part of said push rod (16) (col. 5, lines 61 - 63), said barrel (12) comprises inwardly projecting pins (col. 6, lines 11 - 12), and wherein said external threads cooperate with said inwardly projecting pins (col. 6, lines 10 - 12).

Regarding claim 16, the axial extent of said external threads along said knob (22) is limited and said external threads thereby cooperate with said inwardly projecting pins over a limited distance (col. 6, lines 25 - 30).

Regarding claim 17, as discussed above, Chambers does not disclose a latch pin and latch finger, but Figueroa discloses a latch to prevent movement of the plunger. Similar to the other latch pin and latch finger configuration in Figueroa to connect the proximal end 93 of the cannula to the barrel 20, it would be obvious to place the latch finger on the barrel 20 and the latch pin on the push rod. Also, if such a latch were used to prevent inadvertent movement during shipping, as disclosed by Figueroa, it would be obvious to center the latch over the slot so that the user can easily remove it prior to application of force.

Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chambers, U.S. Patent No. 6,059,791, in view of Weber, U.S. Patent No. 6,899,717.

Regarding claim 19, Chambers discloses a method comprising providing an insertion device comprising a plunger rod assembly, an inserter housing, and a control knob assembly; providing a cartridge having a folded intraocular lens positioned therein; loading said cartridge into said inserter housing; actuating said control knob assembly to

couple a distal end of said plunger rod assembly with said intraocular lens; inserting a distal end of said cartridge into said eye; applying force to said control knob assembly to move said intraocular lens through said cartridge and partially eject said intraocular lens from said cartridge; applying a force to said control knob assembly to eject said intraocular lens into said eye; and removing said distal end of said cartridge from said eye (col. 2, lines 5 – 31; col. 5, lines 39 – 44; col. 6, lines 10 - 20). In regard to actuating a latch and pin mechanism of said plunger rod assembly and removing said force to said control knob assembly without causing movement of said plunger rod assembly, as discussed above, Weber discloses what can be considered a latch pin and latch finger assembly. Figures 11A and 11B in Weber show that upon application of force, the latch assembly locks movement of the plunger thereby preventing proximal longitudinal movement. With the latch assembly in Weber, removal of force to the control knob assembly would not cause movement of the plunger rod assembly. See Weber, column 7, line 37 – column 8, line 5. It would be obvious to combine these two references for the same reasons it would be obvious to combine Chambers with Figueroa: they involve the same field of endeavor, and Weber overcomes the weaknesses of Chambers, i.e. preventing inadvertent movement of the plunger rod assembly by application of a latch assembly.

Regarding claim 20, Chambers discloses the step of biasing the plunger rod assembly against forward travel (col. 6, lines 39 - 45).

Regarding claim 21, the latch configuration in Weber is obviously released so that another lens can be inserted.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Weber**, U.S. Patent No. **6,899,717**.

Claim 23: As discussed above, Weber's figures 11A and 11B show a method of inserting an intraocular lens. The method comprises applying pressure on an insertion device 170 to advance an intraocular lens 101 through said insertion device; maintaining pressure on said insertion device until said intraocular lens projects from a distal end of said insertion device; advancing a plunger rod assembly of said insertion device so that a leading edge of a latch pin 175 on said plunger rod assembly engages an angled tip 178 of a latch finger (161 and 176) on a housing of said device, thereby locking said insertion device to prevent retraction of said intraocular lens. Whether or not the lens is totally or partially ejected by the time the latch pin and latch finger engage one another depends on the location of the latch pin or tab 175. Weber discloses that the latch pin 175 can be placed where desired, i.e. "where positioned properly". See Weber, column 7, line 52. Figures 11A-11B do not specifically show a patient's eye, but it would be obvious that upon releasing pressure on said insertion device, the user would position the intraocular lens in a patient's eye. Also, depending on where the latch pin or tab 175 is located, when the plunger rod assembly is further advanced, the latch finger disengages from said latch pin, thereby unlocking said insertion device, and releasing said intraocular lens into said patient's eye (figure 11B).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Thomas Andersen whose telephone number is (571) 272-8024. The examiner can normally be reached on M-F 8AM-4:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Thomas Andersen
May 24, 2006



MICHAEL J. HAYES
PRIMARY EXAMINER